AUG 2 2 2001

K012757

ATTACHMENT 7 - 510(k) Summary

1. **Applicant's Name and Address**

Straumann USA (on behalf of Institut Straumann AG)
Reservoir Place
1601 Trapelo Road
Waltham, MA 02451
Telephone Number: 781-890-0001
Fax Number: 781-890-6464
Contact Person: Linda Jalbert
Director, Regulatory Affairs

2. **Name of the Device**

Trade Name:	ITI® DENTAL IMPLANT SYSTEM
Common Name:	Endosseous dental implants
Classification Name:	Endosseous dental implants 21 CFR 872.3640

3. **Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)**

ITI Self-Tapping Implants (K003271)
ITI Temporary Abutment (K990342)

4. **Description of the Device**

The ITI tapered implant is an addition to the currently distributed ITI Dental Implant System. The tapered implant is a solid screw with a TPS (titanium plasma sprayed) coating or an SLA surface (grit blasted then acid etched). The implants are composed of Grade 4 commercially pure titanium and is available in a range of lengths and diameters.

This submission also includes abutments and healing caps which are used as accessories to dental implants.

5. **Intended Use of the Device**

The ITI tapered implant is intended for immediate, delayed, or conventional placement in the maxillary and/or mandibular arches to support crowns, bridges or overdentures in edentulous or partially edentulous patients.

6. **Basis for Substantial Equivalence**

The subject ITI self-tapping tapered dental implant is substantially equivalent to the previously cleared ITI self-tapping implant. The intended use is identical to the predicate device. The self-tapping implant is cleared for immediate, delayed, or conventional placement in the maxillary and/or mandibular arches to support crowns, bridges or overdentures in edentulous or partially edentulous patients. This is the identical intended use as the subject ITI tapered implant.

The subject tapered ITI implant has the same material composition and the same surface treatment as previously cleared ITI implants. In addition, the design of the tapered implant is similar to, and in some respects identical to, the previously cleared self-tapping ITI implant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2001

Ms. Linda Jalbert
Director of Regulatory Affairs
Straumann USA
Reservoir Place,
1601 Trapelo Road
Waltham, Massachusetts 02154

Re: K012757
Trade/Device Name: ITI Dental Implant System
Regulation Number: 872.3640
Regulatory Class: III
Product Code: DZE
Dated: August 15, 2001
Received: August 17, 2001

Dear Ms. Jalbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012757

Device Name: ITI® Dental Implant System

Indications For Use:

ITI® tapered implants are intended for immediate, delayed, or conventional placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for MSR

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012757